

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re: DePUY ORTHOPAEDICS, INC.,)
ASR HIP IMPLANT PRODUCTS)
LIABILITY LITIGATION) MDL Docket No.
-----) 1:10-md-2197
This Document Applies to All)
Cases)

CROSS-NOTICED IN VARIOUS OTHER ACTIONS

PROTECTED - PURSUANT TO PROTECTIVE ORDER

THE VIDEOTAPED DEPOSITION OF PAUL VOORHORST

December 3, 2012

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4 The videotaped deposition of PAUL VOORHORST,
5 called by the Plaintiffs for examination, taken
6 pursuant to the Federal Rules of Civil Procedure of
7 the United States District Courts pertaining to the
8 taking of depositions, taken before CORINNE T.
9 MARUT, C.S.R. No. 84-1968, a Notary Public within
10 and for the County of DuPage, State of Illinois,
11 and a Certified Shorthand Reporter of said state,
12 at the offices of Barnes & Thornburg LLP, Suite
13 500, 110 East Wayne Street, Fort Wayne, Indiana, on
14 December 3, 2012, commencing at 9:00 a.m.

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11 VIDEOTAPED BY:

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14 REPORTED BY: CORINNE T. MARUT, C.S.R. No. 84-1968

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1 data sets. There's a lot of different estimates
2 that, you know, would be made available. It could
3 be very confusing. I mean, that would be one way
4 that I think it might be harmful where the -- what
5 estimate would we send out, would we send out the
6 one from our clinical trials, would we send out the
7 ones from the National Joint Registries. I don't
8 know what the surgeons would do with that
9 information.

10 Q. Well, DePuy made the decision that it
11 would use the numbers from the National Joint
12 Registry when it announced the recall, correct?

13 A. Yes.

14 MR. SOCHA: Just object to the form of the
15 question, vague and ambiguous.

16 BY MR. DEVINE:

17 Q. It didn't think that that was confusing,
18 did it?

19 A. So, we did reference the National Joint
20 Registry results from the UK when we recalled the
21 product. And that was, you know, the largest,
22 really the largest data set that we had available
23 to us at that time I believe.

24 Q. Is there any larger data set available

1 that have been done by DePuy are listed on that
2 document.

3 MR. SOCHA: That is something for the document
4 review team to deal with, not this witness.

5 MR. DEVINE: All right. Then I'll take their
6 deposition.

7 MR. SOCHA: I'm happy to -- well, never mind.

8 MR. DEVINE: All right.

9 BY MR. DEVINE:

10 Q. The Kaplan-Meier analysis that was done
11 earlier this year, you have no idea what the
12 results of that are, correct?

13 A. I don't.

14 Q. What about the one that was done before
15 that, do you have any knowledge of the results of
16 that?

17 A. I believe that there were -- again,
18 there were documents that I reviewed in preparation
19 for this that I do recall seeing survival,
20 Kaplan-Meier survival curves for from DOTS. I just
21 don't recall the exact survival estimates on that
22 document.

23 Q. I'm going to mark as Exhibit 18 this
24 document.

1 (WHEREUPON, a certain document was
2 marked Voorhorst Deposition Exhibit
3 No. 18, for identification, as of
4 12-03-2012.)

5 BY MR. DEVINE:

6 Q. Does this document represent a
7 Kaplan-Meier analysis that's been done from the
8 DePuy DOTS database?

9 A. Yes, it does, for the ASR XL.

10 Q. And does this document appear on the
11 list that was given to us?

12 A. I'm -- I don't know what's on that list.

13 Q. All right. Could you look at the
14 exhibit. And this Bates number is CLINICAL STUDIES
15 leading zero 1553.

16 MR. SOCHA: We need the DePuy number. Do you
17 have the DePuy number for this document?

18 MR. DEVINE: I don't believe that this
19 document has a DePuy number.

20 BY MR. DEVINE:

21 Q. Let me ask you. Is this a document that
22 you reviewed in preparation for your deposition
23 here today?

24 A. If it's not the exact document, I did

1 review a document that looks very similar to this.

2 Q. And that document had a database lock
3 date of 09 September 2011?

4 A. I don't recall the lock date.

5 Q. Okay. What is this document?

6 A. So, this document is summarizing the
7 results from the DePuy ASR as recorded in the DOTS
8 registry as of September of 2011.

9 Q. Who performed this?

10 A. I believe I would have worked with Mike
11 Stout in our SAS programming group to help me put
12 this together.

13 Q. You believe that or you know that?

14 A. I believe that.

15 Q. Okay. Based on what?

16 A. Based on my recollection and the fact
17 that quite often when I do need to get analyses
18 performed out of the DOTS database, I would talk to
19 Mike about it.

20 Q. All right. And you said that you did
21 this with Mike Stout. So, you both worked on it
22 together?

23 A. Right.

24 Q. What part did you do and what part did

1 Mike Stout do?

2 A. So, I would have reviewed the
3 information that was coming from Mike as it
4 pertains to this analysis.

5 Q. You would have reviewed the results,
6 correct?

7 A. Yes.

8 Q. He would have performed the analysis?

9 A. Yes.

10 Q. All right. And when was this performed?

11 A. Sometime after September 9 of 2011, but
12 I don't know the exact date.

13 Q. All right. Well, that gives about a
14 year and two months to work with. So, within that
15 time, can you give me a better idea?

16 A. I would assume that this happened quite
17 soon after the database lock, within a month or so.

18 Q. But you don't know?

19 A. I don't know for sure. But if I had
20 requested an analysis, it doesn't make sense to me
21 that we would have gone back longer than a month,
22 because, as we talked about, we extract the data on
23 a monthly basis.

24 Q. In preparation for your deposition here

1 today, did you investigate when this study was
2 performed?

3 A. This study?

4 Q. I'm sorry. This analysis.

5 A. I did not.

6 Q. All right. And, again, I would say that
7 as DePuy's person most knowledgeable, we would
8 expect that you would be familiar with the
9 Kaplan-Meier analyses that have been done,
10 including the dates that they were performed.

11 And I would again urge you to overnight
12 to familiarize yourself with the information about
13 these Kaplan-Meier analyses so that tomorrow we can
14 have a more informed discussion about the
15 Kaplan-Meier analyses.

16 I understand that this is based on 14
17 centers, is that correct?

18 A. Yes.

19 Q. Which of those 14 centers?

20 A. I don't have -- I don't recall which
21 centers are using this product.

22 Q. All right. And in preparation for your
23 deposition here today, you didn't investigate which
24 centers are the ones that were being reported in

1 this Kaplan-Meier analysis, is that correct?

2 A. No. My understanding of the deposition
3 was that I was prepared to discuss the results from
4 Kaplan-Meier analyses. Not necessarily memorize
5 which sites were involved in producing or providing
6 data that goes into this analysis.

7 Q. All right. This shows a mean follow-up
8 of 2.23 years, correct?

9 A. That's correct.

10 Q. With a range of zero to 5.12 years,
11 correct?

12 A. That's correct.

13 Q. What does follow-up mean here?

14 A. Follow-up in this means that the
15 patients were returned to clinic and it's simply
16 the elapsed time from the time that they had their
17 total hip replacement to the time that they
18 returned to clinic to be evaluated.

19 Q. All right. And this shows 38 revisions
20 within the population of -- of 455 hips, correct?

21 A. That's correct.

22 Q. Now, if you turn to the second page,
23 this shows a Kaplan-Meier survival curve, correct?

24 A. That's correct.

1 Q. And under the Kaplan-Meier survival
2 curve, it gives a description of the data that
3 shows that the survival estimate at 4.57 years is
4 64.2 percent, correct?

5 A. That's correct.

6 Q. And that means that 35.8 percent are
7 expected to fail by 4.57 years, correct?

8 A. That's correct.

9 Q. And this gives a confidence interval
10 between 50.46 and 75.68, correct?

11 A. That's correct.

12 Q. So, that means within a confidence
13 interval somewhere between 25 and 50 percent of
14 ASR XLs would be expected to fail by 4.7 years --
15 4.57 years, correct?

16 A. That's the estimate for how many would
17 have needed revision at that time, yes.

18 Q. All right. And then if you turn to two
19 pages in, this is the one that starts with
20 "US 04062 ASR XL"?

21 A. Yes.

22 Q. What's your understanding of this
23 Kaplan-Meier analysis?

24 A. So, this -- make sure we are on the --

1 so, the page I'm looking at has -- starts out
2 talking about nine centers, 130 hips.

3 Are we on the same page? Oh, I don't
4 ask questions.

5 MR. SOCHA: You can ask questions to clarify.

6 THE WITNESS: Okay.

7 BY THE WITNESS:

8 A. Can you clarify the page? Are we
9 looking at the one that starts out with nine
10 centers?

11 BY MR. DEVINE:

12 Q. We are, yes.

13 A. Okay. So, there is no Kaplan-Meier
14 analysis on this page, but it's basically
15 summarizing the fact that there were 130 ASR XL
16 hips implanted between that date range, the
17 demographics there for gender; and the mean
18 follow-up was at the time that this report and the
19 database was locked in September of 2011, the mean
20 follow-up was 2.63 years, range 0.06 to 4.73 years.
21 There were 11 revisions, which is calculated to be
22 8.5 percent.

23 Q. All right. And, again, follow-up means
24 the last time they actually came into the clinic,

1 correct?

2 A. That's correct.

3 Q. And then if you skip three more pages to
4 the one that starts "US XL DOTS and 040623 ASR XL"
5 with 23 centers?

6 A. Right. So, there is 23 centers that
7 were involved in providing data in either DOTS or
8 04062. That was 554 hips in total implanted
9 between those dates, mean follow-up 2.2 years,
10 range 0 to 5.12 years, 49 revisions, 8.8 percent.

11 Q. So, this is a combination of the two
12 analyses that we looked at previously, correct?

13 A. Yes.

14 Q. And if you turn the page, the -- under
15 the Kaplan-Meier curve it gives a description of
16 the survival estimates and here it shows a
17 63 percent survival estimate at 4.57 years,
18 correct?

19 A. That's correct.

20 Q. So, again, that means that 37 percent
21 are expected to fail at 4.57 years, correct?

22 A. The estimated revision rate at that time
23 would be 37 percent. That's correct.

24 Q. And within the confidence interval, that

1 of ASR results in other joint registries as well.

2 Q. So, let's talk about the joint
3 registries.

4 First of all, what are joint registries
5 for people --

6 A. Okay.

7 Q. -- jurors who may see this tape?

8 A. Well, the term I think is used
9 differently. So, it's important to understand that
10 there is some large differences between the
11 National Joint Registries that some countries have
12 and the reason that it's important is because the
13 capture, the data capture rate in those countries
14 is quite high.

15 So, the quality of the data I believe is
16 quite good as opposed to there are also, you know,
17 institutional, what are referred to as joint
18 registries from specific institutions or other
19 countries even where it's not a mandate and I would
20 say that the quality or the capture rate of the
21 data is suspect.

22 Q. So, examples of National Joint
23 Registries with this high quality data would
24 include England and Wales?

1 A. I think that they have a good high
2 quality national registry, yes.

3 Q. Do any of the Scandinavian countries
4 have?

5 A. They do.

6 Q. Australia?

7 A. Australia as well, yes.

8 Q. An example of an institutional registry,
9 Kaiser, would that be an institutional registry?

10 A. It would, yes.

11 Q. And can you give me some other examples
12 of American registries, if there are any?

13 A. There are. And, again, I'm not -- I
14 don't know a lot of the details behind them, but I
15 do know that the Mayo Clinic has their own joint
16 registry. I believe the Cleveland Clinic has a
17 joint registry. New England Baptist Hospital in
18 Boston has a registry. Hospital for Special
19 Surgery has a registry. And I'm sure there are
20 others.

21 Q. Henrik Malchau?

22 A. Yes.

23 Q. How do I say that name?

24 A. It's Malchau.

1 anywhere, practice medicine anywhere in the
2 United States?

3 A. I don't know.

4 Q. And then Gary Warriner?

5 A. Gary was a biostatistician based in
6 Leeds.

7 Q. And at the time of this white paper, at
8 the time it was authored, did he report to you?

9 A. I'm not sure exactly when this was
10 authored.

11 Q. I see a 2011 copyright on the second
12 page.

13 A. I don't think so. I think he was
14 reporting to Carleton at that time.

15 Q. And that would be Carleton Southworth?

16 A. Yes.

17 Q. Did Mr. Southworth then report to you?

18 A. He did.

19 Q. So, he was an indirect report to you?

20 A. Yes.

21 Q. And if we go to where I've highlighted
22 it on the first page about eight or nine --

23 A. Yes.

24 Q. -- lines down. Let me just read it for

1 the record.

2 "National joint registries provide
3 valuable and generalizable information on the
4 revision rates/survivorship of newer and older
5 implants alike."

6 First of all, do you agree with that
7 sentence?

8 A. I do.

9 Q. Okay. And then it continues, "Typically
10 they include large cohorts with contributions from
11 all surgeons, irrespective of experience level."

12 Again, is that accurate to your
13 understanding?

14 A. It is.

15 Q. And "These data sources include the
16 Australian Orthopaedic Association National Joint
17 Replacement Registry (AOA NJRR) and the National
18 Joint Registry for England and Wales."

19 A. Yes.

20 Q. And you agree that those are three
21 sources of the data?

22 A. Yes. Well, there are two.

23 Q. There are two I guess. Australian and
24 the --

1 being asked to review something through our -- by
2 our communications group.

3 Q. And you see that there is a statement on
4 this ad that says "99.2 Percent Survivorship"?

5 A. Yes.

6 Q. And there is a reference to the National
7 Joint Registry for England and Wales?

8 A. Yes.

9 Q. What does that mean?

10 A. So, I would interpret that to mean that
11 there was a 99.2 Kaplan-Meier survivorship estimate
12 of this particular product, the ASR XL, based on
13 the data that was extracted or provided to us by
14 the U.K. National Joint Registry in 2008.

15 Q. And, in fact, there wasn't a
16 99.2 percent Kaplan-Meier survivorship estimate
17 done?

18 A. That's -- that's correct.

19 Q. So, this ad is in error?

20 A. It was certainly a misunderstanding I
21 think between Gary Warriner and myself as to what
22 that 99.2 percent was.

23 Q. If you had seen this ad before it ran,
24 would you have told people don't run it?

1 A. I would have definitely asked questions
2 about -- so, I did see this ad before it ran, and I
3 remember e-mailing Gary to confirm the accuracy of
4 those results.

5 Q. And he told you that, yes, there was a
6 99.2 percent Kaplan-Meier estimate?

7 A. He did not say Kaplan-Meier I don't
8 believe. I think what he said was that there was a
9 99.2 percent survival rate.

10 Q. After this ad ran, there was at least
11 one surgeon, Dr. Sampson, who contacted Mr. Berman.
12 You know Mr. Berman?

13 A. I do.

14 Q. And -- actually, I take that back. I
15 believe he contacted Dr. Vail and Dr. Vail
16 forwarded the communication to Mr. Berman.

17 But Dr. Sampson expressed incredulity at
18 this claim. Did anyone ever tell you about that?

19 A. No.

20 Q. In that communication Dr. Sampson told
21 Dr. Vail that his personal experience with ASR was
22 very much different and very much worse than this
23 claim of 99.2 percent and he also referenced a
24 Dr. Prieto.